

Government grants, cooperative agreements, and contracts for pandemic countermeasure influenza A (H5N1) vaccine used and administered in accordance with this declaration, irrespective of the means of distribution.

This declaration shall apply to all product administered during the effective period of the declaration in the United States by program planners and qualified persons covered by this declaration, pursuant to any means of distribution.

This declaration shall subsequently refer to the countermeasures identified above as "Covered Countermeasures."

## II. Category of Disease (as Required by Section 319F-3(b)(2)(A) of the Act)

The category of disease for which I am recommending the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian influenza A (H5N1) virus following exposure to the virus.

## III. Effective Time Period (as Required by Section 319F-3(b)(2)(B) of the Act)

The effective period of time of this Declaration commences on December 1, 2006 and extends through February 28, 2010.

## IV. Population (as Required by Section 319F-3(b)(2)(C) of the Act)

Section 319F-3(a)(4)(A) confers immunity to manufacturers and distributors of the Covered Countermeasure, regardless of the defined population.

Section 319F-3(a)(3)(C)(i) confers immunity to covered persons who could be program planners or qualified persons with respect to the Covered Countermeasure only if a member of the population specified in the declaration administers or uses the Covered Countermeasure and is in or connected to the geographic location specified in this declaration, or the program planner or qualified person reasonably could have believed that these conditions were met.

The populations specified in this Declaration are the following: (1) All persons who use a Covered Countermeasure or to whom such a Covered Countermeasure is administered as an Investigational New Drug in a human clinical trial conducted directly by the Federal Government, or pursuant to a contract, grant or cooperative agreement with the Federal Government; (2) all persons who use a Covered Countermeasure or to whom such a Countermeasure is administered in a pre-pandemic phase,

as defined below; and/or (3) all persons who use a Covered Countermeasure, or to whom such a Covered Countermeasure is administered in a pandemic phase, as defined below.

## V. Geographic Area (as Required by Section 319F-3(b)(2)(D) of the Act)

Section 319F-3(a) applies to the administration and use of a Covered Countermeasure without geographic limitation.

## VI. Other Qualified Persons (as Required by Section 319F-3(i)(8)(B) of the Act)

With regard to the administration or use of a Covered Countermeasure, Section 319F-3(i)(8)(A) of the Act defines the term "qualified person" as a licensed individual who is authorized to prescribe, administer, or dispense the countermeasure under the law of the State in which such Covered Countermeasure was prescribed, administered or dispensed. Additional persons who are qualified persons pursuant to section 319F-3(i)(8)(B) are the following: None.

## VII. Additional Time Periods of Coverage After Expiration of Declaration (as Required by Section 319F-3(b)(3)(B) of the Act)

A. I have determined that, upon expiration of the time period specified in Section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition of the Covered Countermeasure, including the return of such product to the manufacturer, and for covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F-3(a) of the Act shall extend for that period.

B. The Federal Government shall purchase the entire production of Covered Countermeasures under the contracts specifically listed by contract number in section I for the stockpile under section 319F-2 of the Act, and shall be subject to the time-period extension of section 319F-3(b)(3)(C). Production under future contracts for the same vaccine will also be subject to the time-period extension of section 319F-3(b)(3)(C).

## VIII. Amendments

This Declaration has not previously been amended. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-2(b)(4) of the Act.

## IX. Definitions

For the purposes of this declaration, "pre-pandemic phase" means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas.

For the purposes of this declaration, "pandemic phase" means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Dated: January 26, 2007.

**Michael O. Leavitt,**

Secretary of Health and Human Services.

## Appendix I

### LIST OF U.S. GOVERNMENT CONTRACTS—COVERED H5N1 VACCINE CONTRACTS

[January 26, 2007]

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI-0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C

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